REMARKS

- Claims 1, 3-7 and 9 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 3,491,070 (Weaver).

The examiner maintains the rejection of claims 1, 3-7 and 9 as being anticipated by Weaver. The examiner characterizes Weaver as disclosing a pressure sensitive adhesive obtained by combining monomers to form polymers comprising 80-96% 2-ethylhexyl acrylate and 2.0-19% of octyl acrylamide and as further containing ammonium persulfate. The examiner maintains the position that ammonium persulfate is a therapeutic agent, referring the US 5,827,505 to support this position.

Prior to addressing the merits of this rejection, applicants' note that in their prior response the adhesive of Weaver was erroneously said to contain, as a required and essential component, methylacrylamide monomer. Rather, Weaver discloses, as a required and essential component, methacrylamide monomer. Applicants apologize for this inadvertent typographical error, and appreciate that this error may have led to some confusion, as methylacrylamide would have been interpreted as being an N-substituted acrylamide.

Weaver discloses adhesive compositions that comprise a polymer composition based on a specific acrylate monomer (2-ethylhexyl acrylate) and two specific acrylamide monomers (N-octyl acrylamide and methacrylamide). The adhesive of Weaver contains a polymer based on 2-ethylhexyl acrylate, N-octyl acrylamide and methacrylamide and teaches that all three monomers must be present in the adhesive composition.

Applicants' claim 1 is directed to an adhesive composition comprising an acrylic polymer and a therapeutic agent. The acrylic polymer is made from monomers selected from the group consisting of alkyl acrylate monomer, alkyl methacrylate monomer and polymerizable non-cyclic

nitrogen-containing monomers. The alkyl acrylate monomer and alkyl methacrylate monomers used to prepare the polymer are further characterized as having up to about 18 carbon atoms in the alkyl group. The polymerizable non-cyclic nitrogen-containing monomers are further characterized as being selected from the group consisting of N-substituted acrylamide monomers, N-substituted methacrylamide monomers, vinylacetamides, nitriles, and mixtures thereof. The acrylic polymer required for use comprises, on a dry weight basis of the total monomer weight of the polymer, from about 50 to about 98% of the alkyl acrylate monomers and/or alkyl methacrylate monomers and from about 2 to about 50% of the polymerizable non-cyclic nitrogen-containing monomers, lacks functional groups containing reactive hydrogen moieties and contains no post-polymerization chemical crosslinking.

Applicants disagree that the claimed invention is anticipated by Weaver.

Weaver teaches, as a required and essential polymer prepared using methacrylamide monomer. Again, the polymer of Weaver must contain only 2-ethylhexyl acrylate, N-octyl acrylamide and methacrylamide, and requires all three. Applicants' polymer is prepared from alkyl acrylate monomer and alkyl methacrylate monomers having up to about 18 carbon atoms in the alkyl group, N-substituted acrylamide monomers, N-substituted methacrylamide monomers, vinylacetamides, and nitriles, and must contain 50 to about 98% of the alkyl acrylate and/or alkyl methacrylate monomers and from about 2 to about 50% of the recited nitrogen-containing monomers. No other monomers are included. Methacrylamide, which is not N-substituted, is not included as a possible monomer component of applicants' acrylic polymer.

Applicants also disagree with the examiner's position that Weaver teaches an adhesive containing a therapeutic agent. In Example 1 of the Weaver patent, an adhesive polymer is prepared by combining water, dispersant, emulsifier, catalyst and monomer mixture in the

amounts set forth in Table 1. Ammonium persulfate is used as a polymerization initiator in an amount of 0.18 parts and would be completely consumed in the polymerization. Weaver does not disclose an adhesive comprising ammonium persulfate as urged by the examiner. The examiner is referred to the accompany literature (Paul Mentor; Bio-Rad, Tech Note 1156; Acrylamide Polymerization – A Practical Approach, second page, last paragraph of col. 1:

> Ammonium persulfate is also very hygroscopic. This property is particularly important, since ammonium persulfate begins to break down almost immediately when dissolved in water. Therefore, the accumulation of water in ammonium persulfate results in a rapid loss of reactivity. This is why ammonium persulfate solutions should be prepared fresh daily. Persulfate is consumed in the polymerization reaction. Excess persulfate can cause oxidation of proteins and nucleic acids. This oxidation problem can be avoided if inhibitor free gell-forming reagents are used and ammonium persulfate is used at the recommended levels. Emphasis added.

Weaver (i) fails to disclose an adhesive comprising applicants' required polymer and (ii) fails to disclose an adhesive comprising a therapeutic agent.

In order to anticipate, the reference must disclose all elements of the claim within the four corners of the document. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegall Bros. v. Union Oil Co. of California*, 814 F.2d, 628, 631 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 827 (1987). Weaver fails to disclose a polymer prepared using only alkyl acrylate monomer and alkyl methacrylate monomers having up to about 18 carbon atoms in the alkyl group, N-substituted acrylamide monomers, N-substituted methacrylamide monomers, vinylacetamides, and nitriles. As such, Weaver does not contain each of the required limitations of applicants' claimed invention and, as such, fails to anticipate claims 1, 3-7 and 9.

The examiner's position (Office action of March 12, 2009, page 4, line13 to page 5, line 1) that "the expression 'comprising' in the preamble of claim 1 does not exclude other elements or materials even in major amounts including other polymerizable monomers in the adhesive composition" and that the "ranges as claimed permit the presence of other monomers because if 60% of the acrylate monomer is used and 30% on the non-cyclic nitrogen-contain monomer, then this will form 90% of the polymer, and the remaining 10% can be another monomer. Therefore methylacrylamide (sic; methacrylamide) monomer disclosed by the reference is with the scope of the present claims as an essential element that is a nitrogen-containing monomer" is without merit and ignores applicants recited claim language, and the teachings of the applied Weaver reference.

Applicants claim an adhesive comprising (1) an acrylic polymer and (2) a therapeutic agent.

The acrylic polymer is then defined as being a polymer prepared from monomers selected from the group consisting of alkyl acrylate monomers, alkyl methacrylate monomers, polymerizable non-cyclic nitrogen-containing monomers and mixtures thereof, and further limit the polymerizable non-cyclic nitrogen-containing monomers are selected from the group consisting of N-substituted acrylamide monomers, N-substituted methacrylamide monomers, vinylacetamides, nitriles, and mixtures thereof. Applicants claimed polymer cannot comprise a polymer prepared from 2-ethylhexyl acrylate, N-octyl acrylamide and methacrylamide.

Claims 1, 3-7 and 9 are not anticipated by Weaver. Reconsideration and withdrawal of this Section 102 rejection is requested.

- Claims 1, 3-6, 9-14 and 22 are rejected under 35 U.S.C. § 102(b) as being anticipated by EP 0 531 938.

The examiner continues to interpret applicants' claims as requiring polymer prepared

from monomers selected from the group consisting of alkyl acrylate monomer, alkyl methacrylate monomer and polymerizable non-cyclic nitrogen-containing monomer, and as further allowing other alkyl acrylate monomers and/or alkyl methacrylate monomers, which include methacrylamide. As discussed above, this is an incorrect interpretation of applicants' claimed subject matter.

Again, applicants' claim 1 is directed to an adhesive composition comprising an acrylic polymer and a therapeutic agent. The acrylic polymer is made from monomers selected from the group consisting of alkyl acrylate monomer, alkyl methacrylate monomer and polymerizable non-cyclic nitrogen-containing monomers. The alkyl acrylate monomer and alkyl methacrylate monomers used to prepare the polymer are further characterized as having up to about 18 carbon atoms in the alkyl group. The polymerizable non-cyclic nitrogen-containing monomers are further characterized as being selected from the group consisting of N-substituted acrylamide monomers, N-substituted methacrylamide monomers, vinylacetamides, nitriles, and mixtures thereof. The acrylic polymer required for use comprises, on a dry weight basis of the total monomer weight of the polymer, from about 50 to about 98% of the alkyl acrylate monomers and/or alkyl methacrylate monomers and from about 2 to about 50% of the polymerizable non-cyclic nitrogen-containing monomers, lacks functional groups containing reactive hydrogen moieties and contains no post-polymerization chemical crosslinking.

Applicants disagree that the claimed invention is anticipated by EP'938.

EP'938 discloses a pressure sensitive adhesive formed using an acrylic ester-based polymer and a liquid component and then crosslinking the polymer to allow it to gell (see, e.g., page 2, lines 55-59 of EP'938).

The examiner ignores the relevant passages and the EP'938 disclosure as a whole. As

noted above, applicants' acrylic polymer lacks functional groups containing reactive hydrogen moieties and contains no post polymerization chemical crosslinking. In contrast, EP'938 discloses a crosslinked pressure sensitive adhesive gel material. The examiner is referred to the monomers recited on page 4, lines 24 et seq. and to the disclosure at page 4, lines 46-50 of EP'938:

> Of such various acrylic ester-based polymers, copolymers obtained by copolymerizing an alkyl (meth)acrylate and at least one of the above-described carboxyl group-containing monomers and hydroxyl group-containing monomers, as essential components, and if required one or more of the other monomers described above are advantageously used in the present invention from the standpoint of control of the amount of crosslinking sites or control of tackiness properties.

The examiner is again referred to the examples, which use acrylic acid (examples 1-6) and 2-hydroxyethyl acrylate (7 and 8).

The examiner is also referred to page 5, lines 7-20, of EP'938 which teaches that the acrylic gel "is crosslinked by a suitable crosslinking means" which crosslinking may be accomplished by a physical treatment or by a chemical treatment using a crosslinking agent. As can be seen in the examples, isocyanate is added postpolymerization to affect crosslinking.

EP'938 fails to:

(i) teach a pressure sensitive adhesive comprising an acrylic polymer that lacks functional groups containing reactive hydrogen moieties and contains no post polymerization chemical crosslinking,

(ii) disclose an adhesive comprising applicant's required polymer, and

(iii) fails to disclose such an adhesive that also comprises a therapeutic agent as required in the practice of applicants' invention.

The polymer of EP'938 does not contain each of the required limitations of applicants' claimed invention and, as such, fails to anticipate claims 1, 3-6, 9-14 and 22.

Claims 1, 3-6, 9-14 and 22 are not anticipated by EP'938. Reconsideration and withdrawal of this Section 102 rejection is requested.

- Claims 1, 3-7, 9-14 and 22 are rejected under 35 U.S.C. § 103 (a) as being obvious over EP 0 531 938 in view of US 3,494,070 (Weaver).

EP '938 is cited as teaching a medical preparation for percutaneous absorption of drugs. The examiner urges that it would have been obvious to the skilled artisan to replace the acrylamide monomer of EP '938 with octyl acrylamide disclosed in Weaver.

Applicants disagree. The claimed invention would not have been obvious from the combined disclosures of EP '938 and Weaver. Use of octyl acrylamide in the practice of the EP '938 invention would not have resulted in an adhesive comprising a acrylic polymer that lacks functional groups containing reactive hydrogen moieties and contains no post polymerization chemical crosslinking.

Claims 1, 3-7, 9-14 and 22 are not obvious over EP'938 in view of US '070. Reconsideration and withdrawal of this Section 103 rejection is requested.

- Claims 15-17 are rejected under 35 U.S.C. § 103 (a) as being obvious over EP 0 531 938 in view of US 3,494,070 and further in view of 6,139,866 (Chono et al.).

The examiner urges that while EP '938 teaches delivery use of analgesics, sedatives and hypnotic drugs, the use of fentanyl is not explicitly taught. It is, however, the position of the examiner that it would have been obvious to the skilled artisan to replace the analgesic, sedative or hypnotic drugs of EP '938 with fentanyl that is taught in Chono et al. as being suitable for transdermal administration.

Applicants disagree. First and importantly, the combined disclosures of Weaver and EP '938 would not have led to an adhesive comprising an acrylic polymer that lacks functional groups containing reactive hydrogen moieties and contains no post polymerization chemical crosslinking. Use of fentanyl in as a therapeutic agent to be delivered would not have resulted in an adhesive comprising an acrylic polymer that lacks functional groups containing reactive hydrogen moieties and contains no post polymerization chemical crosslinking.

Claims 15-17 are not obvious over EP'938 in view of Weaver and further in view of Chono et al. Reconsideration and withdrawal of this Section 103 rejection is requested.

Claims 18, 19, 21 and 23 are rejected under 35 U.S.C. § 103 (a) as being obvious over

- EP 0 531 938 in view of US 3,494,070 (Weaver) and further in view of in view of US 5,458,885 (Muller et al.).

EP '938 is cited by the examiner as teaching use of two or more alkyl (meth)acrylates in the polymer. Weaver is cited as teaching octyl acrylamide. While the examiner acknowledges that 2-ethylehexyl acrylate and methyl acrylate, as required by claims 18, 19, 21 and 23, are not explicitly taught in the combined disclosures of EP '938 and Weaver, the examiner applies Muller et al. in an attempt to cure this defect. Muller et al. is cited by the examiner as teaching transdermal systems comprising polymer made of methyl acrylate and 2-ethylehexyl acrylate. It is the position of the examiner that it would have been obvious to the skilled artisan to replace the acrylate monomers of EP'935 and Weaver with methyl acrylate and 2-ethylehexyl acrylate disclosed in is taught in Muller et al.

Applicants disagree. The claimed invention would not have been obvious from the combined disclosures of EP '938, Weaver and Muller et al.

Again, and as argued above, the combined disclosures of Weaver and EP '938 would not have led to an adhesive comprising an acrylic polymer that lacks functional groups containing reactive hydrogen moieties and contains no post polymerization chemical crosslinking. There is no suggestion that would motivate the skilled artisan to use only those monomers that would result in an acrylate polymer that lacks functional groups containing reactive hydrogen moieties and contains no post polymerization chemical crosslinking, as such an adhesive would be contrary to the teachings of EP '938. There is no disclosure that would motivate the skilled artisan not use the methacrylamide monomer of Weaver, as such an absence of a required component would be contrary to the teachings of Weaver. The further combination of Muller et al. with the combined disclosures of EP'938 in view of Weaver would not have led the skilled artisan to applicants' claimed adhesive.

Claims 18, 19, 21 and 23 are not obvious over EP'938 in view of Weaver and further in view of Muller et al. Reconsideration and withdrawal of this Section 103 rejection is requested.

Applicants submit that claims 1, 3-7 and 9-22 are in condition to be allowed. Early and favorable action is requested.

Respectfully submitted,

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